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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,985	02/03/2004	Nancy J. Harper	PC10139B	3565

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EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,985	HARPER ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Final Rejection

The Status of Claims

Claims 1-13 are pending.

Claims 1-13 have been rejected.

Claim Rejections-35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 11-13 under 35 U.S.C. 112, second paragraph, has been withdrawn due to the modification made in the amendment.

Claim Rejections-35 USC 101

The rejection of Claims 11-13 under 35 U.S.C. 101, has been withdrawn due to the modification made in the amendment.

Double Patenting Rejection

The rejection of Claims 1-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 13 of U.S. Patent No. 6,727,283 has been withdrawn due to the Terminal Disclaimer filed on 9/15/04.

Claim Rejections-35 USC 103

1. Applicants' argument filed 8/30/04 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rejection of Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doogan et al (U.S. 4,962,128) in view of Howard et al (U.S. 5,597,826) and Johnson (EP0768083).

The rejection of Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doogan et al (U.S. 4,962,128) in view of Howard et al (U.S. 5,597,826) is maintained for the reasons of the record on 8/10/04.

Applicants' Argument

2. Applicants argue the following issues:

1. the Doogan et al has failed to teach the preparation of non-aqueous liquid concentrate compositions of sertraline and has directed to the use of water, ethanol, glycerin as primary diluents in the liquid preparation ;

2. there is no teaching in the Howard et al that would lead the skillful artisan to obtain an essentially non-aqueous liquid concentration of sertraline ;

3. there is no teaching in the Johnson that would lead the skillful artisan to obtain an essentially non-aqueous liquid concentration of sertraline ;

4. applicants' non-aqueous liquid concentrate for oral administration having unique amount and combination of excipients do not suggest in the prior art; and

5. the Examiner has not supplied the motivation to combine the references to achieve the non-conventional, non-aqueous liquid concentrate having the unique amounts and combination of excipients;

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the first and fourth arguments, the Examiner has noted applicants' argument. However, the Doogan et al does teach the composition contains setraline or its pharmaceutically acceptable salt, flavoring agents, and diluents ,such as ethanol, glycerin and various like combinations thereof; also,

the secondary Howard et al reference to supplement the primary reference does disclose that liquid preparations containing sertraline may be prepared by conventional means with pharmaceutically acceptable additives such as non-aqueous vehicles (see col. 22 ,lines 47-55). Furthermore, it is well-known in the art that many liquid preparations of conventional means with pharmaceutically acceptable additives are available depending upon the customer's choice. Therefore, if the skillful artisan in the art had desired to develop the product containing non-aqueous liquid concentrate compositions of sertraline, it would have been obvious for the skillful artisan in the art to have motivated to incorporate Howard et al 's non-aqueous vehicles into the Doogan et al method because, for oral administration, Howard et al does indicate that non-aqueous vehicles can be incorporated in the liquid preparations containing sertraline .

Second, with respect to the second argument, the Examiner has noted applicants' argument. However, the Doogan et al does teach that it is administered in dosages ranging from 50-500 mg /day (see col. 2 , lines 20-21); oral pharmaceutical formulations can be flavored by means of various agents ; the composition contains sertraline with concentration levels ranging from 0.5 % to 90 % by weight of the total compositions (see col. 2 ,lines 45-46) or its pharmaceutically acceptable salt, flavoring agents, and diluents such as ethanol, propylene glycol, and glycerin (see from col. 2 line 65 to col. 3, line 2). Also, the Howard et al reference does teach the dose of 0.3mg to 10mg per kg of body weight per day of the sertraline (see col. 23, lines 33-34) ; Howard et al

reference has indicated that it is possible to prepare the sertraline composition containing pharmaceutically acceptable additives such as non-aqueous vehicles (see col. 22 ,lines 47-55). Both prior art have been commonly dealt with the preparation of the sertraline composition. Therefore, if the skillful artisan had desired to develop the product containing non-aqueous liquid concentrate compositions of sertraline, it would have been obvious for the skillful artisan in the art to have motivated to incorporate Howard et al 's non-aqueous vehicles into the Doogan et al method, thereby ascertaining the claimed dose by routine experimentation. This is because, for oral administration, Howard et al does indicate that non-aqueous vehicles can be incorporated in the liquid preparations containing sertraline.

Third, concerning the third argument, the Examiner has noted applicants' argument. However, the Johnson reference has been withdrawn from the rejection . Therefore, applicants' argument are irrelevant.

Fourth, regarding the fifth argument, the Examiner has noted applicants' argument. However, there is a motivation to combine the references. Doogan et al does disclose the pharmaceutical composition containing sertraline hydrochloride (see col. 1, line 68) with a dose from 25 mg to 200 mg for treating anxiety-related disorders (see col. 2, lines 20-23); in addition, oral pharmaceutical formulations can be flavored by means of various agents ; the composition contains sertraline or its pharmaceutically acceptable salt, flavoring

agents, and diluents such as ethanol, propylene glycol, and glycerin (see from col. 2 line 65 to col. 3, line 2). If elixirs are desired for oral administration , the sertraline may be combined with various flavoring agents 6(see from col. 2 lines 63-67).

Howard et al discloses expressly the pharmaceutical composition containing sertraline hydrochloride (see col. 20, line 31) with a dose from 0.1 mg to 200 mg (see col. 24, lines 7-8), suspending agents, non-aqueous vehicles such as ethyl alcohol, and preservatives (see col. 22, lines 51-56); in addition, oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58). Also, the reference indicates that pharmacologically acceptable anions include methanesulfonate (see col. 20, lines 60-61). Both prior art references are definitively dealt with the pharmaceutical composition containing sertraline hydrochloride with an overlapping dose; both do describe that the pharmaceutical composition containing sertraline hydrochloride may be combined with various pharmaceutically acceptable inert carrier in the form of syrups and solutions. Therefore, if the skillful artisan had desired to develop the product containing non-aqueous liquid concentrate compositions containing sertraline and methanesulfonate as pharmacologically acceptable anions, it would have been obvious for the skillful artisan in the art to have motivated to use Howard et al 's methanesulfonate into the Doogan et al pharmaceutical composition containing sertraline hydrochloride because, for oral administration, both do indicate that non-aqueous vehicles can be incorporated in the liquid preparations containing sertraline . Therefore, there is the motivation to combine

the references rejection references to achieve the non-aqueous liquid concentrate having the unique amounts and combination of excipients by routine experimentations.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11/14/04

Cecilia J. Tsang
Supervisory Patent Examiner
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